

By the Committees on Appropriations; Health, Aging, and Long-Term Care; and Senator Pruitt

309-2348-04

1 A bill to be entitled
2 An act relating to certificate of need;
3 amending s. 395.003, F.S.; providing additional
4 conditions for the licensure or relicensure of
5 hospitals; exempting currently licensed
6 hospitals; amending s. 408.032, F.S.;
7 redefining terms relating to the Health
8 Facility and Services Development Act; deleting
9 the term "regional area"; amending s. 408.033,
10 F.S.; deleting provisions relating to regional
11 area health plans; transferring certain duties
12 from the Agency for Health Care Administration
13 to the Department of Health; deleting an agency
14 responsibility relating to orientation of local
15 health council members; deleting a requirement
16 that local health councils be partly funded by
17 application fees for certificates of need;
18 adding sources of funding for local health
19 councils; amending s. 408.034, F.S.; revising
20 criteria for certificate-of-need review and for
21 issuing licenses to health care facilities and
22 health service providers; revising criteria for
23 the nursing-home-bed-need methodology; amending
24 s. 408.035, F.S.; revising the criteria for
25 reviewing applications for certificate-of-need
26 determinations; amending s. 408.036, F.S.;
27 revising criteria for determining whether a
28 health-care-related project is subject to
29 review; providing that the replacement or
30 relocation of a nursing home is subject to
31 expedited review under specified conditions;

1 revising the criteria for determining whether a
2 project is subject to exemption from review
3 upon request; repealing the exemption for
4 specified services; adding an optional
5 exemption for neonatal intensive care units
6 that meet certain requirements; providing
7 exemptions for adding beds for comprehensive
8 rehabilitation, for beds in state mental health
9 treatment facilities, for beds in state mental
10 health treatment facilities and state mental
11 health forensic facilities, and for beds in
12 state developmental services institutions;
13 revising the criteria for optional exemption of
14 adult open-heart services; requiring the agency
15 to report annually to the Legislature specified
16 information concerning exemptions requested and
17 granted during the preceding calendar year;
18 adding an optional exemption for the provision
19 of percutaneous coronary intervention under
20 certain conditions; requiring health care
21 facilities and providers to provide to the
22 agency notice of the replacement of a health
23 care facility or a nursing home, in specified
24 circumstances, consolidation of nursing homes,
25 the termination of a health care service, and
26 the addition or delicensure of beds; amending
27 s. 408.0361, F.S., relating to compliance with
28 requirements imposed on diagnostic cardiac
29 catheterization services providers; revising
30 the scope of application, to include the
31 compliance required of cardiology services and

1 the licensure of burn units; requiring the
2 Secretary of Health Care Administration to
3 appoint an advisory group to study replacing
4 certificate-of-need review of organ transplant
5 programs with licensure regulation of organ
6 transplant providers; requiring a report to the
7 secretary and the Legislature; requiring the
8 secretary to appoint a work group to study
9 certificate-of-need regulation and changing
10 market conditions related to the supply and
11 distribution of hospital beds; requiring a
12 report to the secretary and the Legislature;
13 amending s. 408.038, F.S.; revising fees
14 assessed on certificate-of-need applications;
15 amending s. 408.039, F.S.; revising the review
16 process for certificates of need; requiring
17 shorter review cycles; deleting a requirement
18 to file a copy of the application with the
19 local health council; deleting a requirement to
20 consider the district health plan in reviewing
21 and taking action on the applications; amending
22 s. 408.040, F.S.; applying the conditions to
23 the issuance of a certificate of need to the
24 issuance of an exemption; providing that
25 certain failures to annually report compliance
26 with certain conditions to receiving a
27 certificate of need or an exemption constitute
28 noncompliance; repealing s. 408.043(5), F.S.,
29 relating to the authority of a sole acute care
30 hospital in a high growth county to add beds
31 without agency review; amending s. 408.0455,

1 F.S.; providing for the rules of the agency
2 which are in effect on June 30, 2004, rather
3 than those in effect on June 30, 1997, to
4 remain in effect; providing an effective date.
5

6 WHEREAS, appropriate access to adult cardiac care is an
7 issue of critical state importance to all residents of the
8 state and to all health service planning districts of the
9 state, and

10 WHEREAS, the certificate-of-need process, for most
11 geographic areas in the state, has provided adequate access to
12 adult open-heart-surgery services to Floridians as well as
13 tourists, business travelers, indigents, and migrant workers
14 who receive such services, and

15 WHEREAS, the number of adult open-heart-surgery
16 programs in certain health service planning districts has not
17 kept pace with the dramatic increase in population in those
18 areas, and

19 WHEREAS, there have been numerous technological
20 advances in the area of primary angioplasty and stent
21 procedures known collectively as percutaneous coronary
22 interventions, and these advanced interventional treatments
23 provide the highest standard of care for people suffering
24 acute myocardial infarctions, and

25 WHEREAS, the success of these interventional treatments
26 requires immediate access (within 1 hour) to hospitals having
27 interventional technology and a backup open-heart-surgery
28 program, and

29 WHEREAS, hospitals that cannot perform percutaneous
30 coronary interventions must resort to the use of
31 thrombolytics, a less effective treatment in many instances,

1 and therefore adults in need of percutaneous coronary
2 interventions are being denied these procedures due to lack of
3 access, and

4 WHEREAS, diagnosis; discharge from the transferring
5 hospital; transfer arrangements, including, but not limited
6 to, insurance and administrative approval; transportation
7 availability; admission to the receiving hospital; staff
8 availability at the receiving hospital; and, most importantly,
9 bed availability at the receiving hospital as well as travel
10 delays to the receiving hospital contribute to the time taken
11 to effectuate a transfer of a cardiac patient, and

12 WHEREAS, the Legislature finds that timely access and
13 availability for every adult in this state, regardless of
14 socioeconomic class or geographic location, to these
15 interventional treatments and open-heart surgery is of
16 critical state concern, especially because myocardial
17 infarctions and related coronary disease are no respecters of
18 location or time, and

19 WHEREAS, to ensure that it provides the quality of care
20 desired, each hospital that qualifies for the exemption
21 provided by this act will be subject to more stringent
22 criteria and will also be subject to continual monitoring by
23 the Agency for Health Care Administration, and

24 WHEREAS, the Legislature intends to ensure that
25 standards of quality are maintained while promoting
26 competition in the provision of adult cardiac care, NOW,
27 THEREFORE,

28
29 Be It Enacted by the Legislature of the State of Florida:

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1 Section 1. Subsections (9), (10), and (11) are added
2 to section 395.003, Florida Statutes, to read:

3 395.003 Licensure; issuance, renewal, denial,
4 modification, suspension, and revocation.--

5 (9) A hospital may not be licensed or relicensed if:

6 (a) The diagnosis-related groups for 65 percent or
7 more of the discharges from the hospital, in the most recent
8 year for which data is available to the Agency for Health Care
9 Administration pursuant to s. 408.061, are for diagnosis,
10 care, and treatment of patients who have:

11 1. Cardiac-related diseases and disorders classified
12 as diagnosis-related groups 103-145, 478-479, 514-518, or
13 525-527;

14 2. Orthopedic-related diseases and disorders
15 classified as diagnosis-related groups 209-256, 471, 491,
16 496-503, or 519-520;

17 3. Cancer-related diseases and disorders classified as
18 diagnosis-related groups 64, 82, 172, 173, 199, 200, 203,
19 257-260, 274, 275, 303, 306, 307, 318, 319, 338, 344, 346,
20 347, 363, 366, 367, 400-414, 473, or 492; or

21 4. Any combination of the above discharges.

22 (b) The hospital restricts its medical and surgical
23 services to primarily or exclusively cardiac, orthopedic,
24 surgical, or oncology specialties.

25 (10) A hospital licensed as of June 1, 2004, shall be
26 exempt from subsection (9) as long as the hospital maintains
27 the same ownership, facility street address, and range of
28 services that were in existence on June 1, 2004. Any transfer
29 of beds, or other agreements that result in the establishment
30 of a hospital or hospital services within the intent of this
31 section, shall be subject to subsection (9). Unless the

1 hospital is otherwise exempt under subsection (9), the agency
2 shall deny or revoke the license of a hospital that violates
3 any of the criteria set forth in that subsection.

4 (11) The agency may adopt rules implementing the
5 licensure requirements set forth in subsection (9). Within 14
6 days after rendering its decision on a license application or
7 revocation, the agency shall publish its proposed decision in
8 the Florida Administrative Weekly. Within 21 days after
9 publication of the agency's decision, any authorized person
10 may file a request for an administrative hearing. In
11 administrative proceedings challenging the approval, denial,
12 or revocation of a license pursuant to subsection (9), the
13 hearing must be based on the facts and law existing at the
14 time of the agency's proposed agency action. Existing
15 hospitals may initiate or intervene in an administrative
16 hearing to approve, deny, or revoke licensure under subsection
17 (9) based upon a showing that an established program will be
18 substantially affected by the issuance or renewal of a license
19 to a hospital within the same district or service area.

20 Section 2. Subsections (9), (13), and (17) of section
21 408.032, Florida Statutes, are amended, and subsection (18) of
22 that section is repealed, to read:

23 408.032 Definitions relating to Health Facility and
24 Services Development Act.--As used in ss. 408.031-408.045, the
25 term:

26 (9) "Health services" means inpatient diagnostic,
27 curative, or comprehensive medical rehabilitative services and
28 includes mental health services. Obstetric services are not
29 health services for purposes of ss. 408.031-408.045.

30 (13) "Long-term care hospital" means a hospital
31 licensed under chapter 395 which meets the requirements of 42

1 C.F.R. s. 412.23(e) and seeks exclusion from the acute care
2 Medicare prospective payment system for inpatient hospital
3 services.

4 (17) "Tertiary health service" means a health service
5 which, due to its high level of intensity, complexity,
6 specialized or limited applicability, and cost, should be
7 limited to, and concentrated in, a limited number of hospitals
8 to ensure the quality, availability, and cost-effectiveness of
9 such service. Examples of such service include, but are not
10 limited to, pediatric cardiac catheterization, pediatric
11 open-heart surgery, organ transplantation, specialty burn
12 units, neonatal intensive care units, comprehensive
13 rehabilitation, and medical or surgical services which are
14 experimental or developmental in nature to the extent that the
15 provision of such services is not yet contemplated within the
16 commonly accepted course of diagnosis or treatment for the
17 condition addressed by a given service. The agency shall
18 establish by rule a list of all tertiary health services.

19 ~~(18) "Regional area" means any of those regional~~
20 ~~health planning areas established by the agency to which local~~
21 ~~and district health planning funds are directed to local~~
22 ~~health councils through the General Appropriations Act.~~

23 Section 3. Section 408.033, Florida Statutes, is
24 amended to read:

25 408.033 Local and state health planning.--

26 (1) LOCAL HEALTH COUNCILS.--

27 (a) Local health councils are hereby established as
28 public or private nonprofit agencies serving the counties of a
29 district ~~or regional area of the agency~~. The members of each
30 council shall be appointed in an equitable manner by the
31 county commissions having jurisdiction in the respective

1 district. Each council shall be composed of a number of
2 persons equal to 1 1/2 times the number of counties which
3 compose the district or 12 members, whichever is greater. Each
4 county in a district shall be entitled to at least one member
5 on the council. The balance of the membership of the council
6 shall be allocated among the counties of the district on the
7 basis of population rounded to the nearest whole number;
8 except that in a district composed of only two counties, no
9 county shall have fewer than four members. The appointees
10 shall be representatives of health care providers, health care
11 purchasers, and nongovernmental health care consumers, but not
12 excluding elected government officials. The members of the
13 consumer group shall include a representative number of
14 persons over 60 years of age. A majority of council members
15 shall consist of health care purchasers and health care
16 consumers. The local health council shall provide each county
17 commission a schedule for appointing council members to ensure
18 that council membership complies with the requirements of this
19 paragraph. The members of the local health council shall
20 elect a chair. Members shall serve for terms of 2 years and
21 may be eligible for reappointment.

22 (b) Each local health council may:

23 1. Develop a district ~~or regional~~ area health plan
24 that permits each local health council to develop strategies
25 and set priorities for implementation based on its unique
26 local health needs. ~~The district or regional area health plan~~
27 ~~must contain preferences for the development of health~~
28 ~~services and facilities, which may be considered by the agency~~
29 ~~in its review of certificate-of-need applications. The~~
30 ~~district health plan shall be submitted to the agency and~~
31 ~~updated periodically. The district health plans shall use a~~

1 ~~uniform format and be submitted to the agency according to a~~
2 ~~schedule developed by the agency in conjunction with the local~~
3 ~~health councils. The schedule must provide for the development~~
4 ~~of district health plans by major sections over a multiyear~~
5 ~~period. The elements of a district plan which are necessary~~
6 ~~to the review of certificate-of-need applications for proposed~~
7 ~~projects within the district may be adopted by the agency as a~~
8 ~~part of its rules.~~

9 2. Advise the agency on health care issues and
10 resource allocations.

11 3. Promote public awareness of community health needs,
12 emphasizing health promotion and cost-effective health service
13 selection.

14 4. Collect data and conduct analyses and studies
15 related to health care needs of the district, including the
16 needs of medically indigent persons, and assist the agency and
17 other state agencies in carrying out data collection
18 activities that relate to the functions in this subsection.

19 5. Monitor the onsite construction progress, if any,
20 of certificate-of-need approved projects and report council
21 findings to the agency on forms provided by the agency.

22 6. Advise and assist any regional planning councils
23 within each district that have elected to address health
24 issues in their strategic regional policy plans with the
25 development of the health element of the plans to address the
26 health goals and policies in the State Comprehensive Plan.

27 7. Advise and assist local governments within each
28 district on the development of an optional health plan element
29 of the comprehensive plan provided in chapter 163, to assure
30 compatibility with the health goals and policies in the State
31 Comprehensive Plan and district health plan. To facilitate

1 the implementation of this section, the local health council
2 shall annually provide the local governments in its service
3 area, upon request, with:

4 a. A copy and appropriate updates of the district
5 health plan;

6 b. A report of hospital and nursing home utilization
7 statistics for facilities within the local government
8 jurisdiction; and

9 c. Applicable agency rules and calculated need
10 methodologies for health facilities and services regulated
11 under s. 408.034 for the district served by the local health
12 council.

13 8. Monitor and evaluate the adequacy, appropriateness,
14 and effectiveness, within the district, of local, state,
15 federal, and private funds distributed to meet the needs of
16 the medically indigent and other underserved population
17 groups.

18 9. In conjunction with the Department of Health ~~Agency~~
19 ~~for Health Care Administration~~, plan for services at the local
20 level for persons infected with the human immunodeficiency
21 virus.

22 10. Provide technical assistance to encourage and
23 support activities by providers, purchasers, consumers, and
24 local, regional, and state agencies in meeting the health care
25 goals, objectives, and policies adopted by the local health
26 council.

27 11. Provide the agency with data required by rule for
28 the review of certificate-of-need applications and the
29 projection of need for health services and facilities in the
30 district.

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1 (c) Local health councils may conduct public hearings
2 pursuant to s. 408.039(3)(b).

3 (d) Each local health council shall enter into a
4 memorandum of agreement with each regional planning council in
5 its district that elects to address health issues in its
6 strategic regional policy plan. In addition, each local
7 health council shall enter into a memorandum of agreement with
8 each local government that includes an optional health element
9 in its comprehensive plan. Each memorandum of agreement must
10 specify the manner in which each local government, regional
11 planning council, and local health council will coordinate its
12 activities to ensure a unified approach to health planning and
13 implementation efforts.

14 (e) Local health councils may employ personnel or
15 contract for staffing services with persons who possess
16 appropriate qualifications to carry out the councils'
17 purposes. However, such personnel are not state employees.

18 (f) Personnel of the local health councils shall
19 provide an annual orientation to council members about council
20 member responsibilities. ~~The orientation shall include~~
21 ~~presentations and participation by agency staff.~~

22 (g) Each local health council is authorized to accept
23 and receive, in furtherance of its health planning functions,
24 funds, grants, and services from governmental agencies and
25 from private or civic sources and to perform studies related
26 to local health planning in exchange for such funds, grants,
27 or services. Each local health council shall, no later than
28 January 30 of each year, render an accounting of the receipt
29 and disbursement of such funds received by it to the
30 Department of Health ~~agency~~. The department ~~agency~~ shall
31 consolidate all such reports and submit such consolidated

1 report to the Legislature no later than March 1 of each year.
2 ~~Funds received by a local health council pursuant to this~~
3 ~~paragraph shall not be deemed to be a substitute for, or an~~
4 ~~offset against, any funding provided pursuant to subsection~~
5 ~~(2).~~

6 (2) FUNDING.--

7 (a) The Legislature intends that the cost of local
8 health councils be borne by ~~application fees for certificates~~
9 ~~of need and by~~ assessments on selected health care facilities
10 subject to facility licensure by the Agency for Health Care
11 Administration, including abortion clinics, assisted living
12 facilities, ambulatory surgical centers, birthing centers,
13 clinical laboratories except community nonprofit blood banks
14 and clinical laboratories operated by practitioners for
15 exclusive use regulated under s. 483.035, home health
16 agencies, hospices, hospitals, intermediate care facilities
17 for the developmentally disabled, nursing homes, health care
18 clinics, and multiphasic testing centers and by assessments on
19 organizations subject to certification by the agency pursuant
20 to chapter 641, part III, including health maintenance
21 organizations and prepaid health clinics.

22 (b)1. A hospital licensed under chapter 395, a nursing
23 home licensed under chapter 400, and an assisted living
24 facility licensed under chapter 400 shall be assessed an
25 annual fee based on number of beds.

26 2. All other facilities and organizations listed in
27 paragraph (a) shall each be assessed an annual fee of \$150.

28 3. Facilities operated by the Department of Children
29 and Family Services, the Department of Health, or the
30 Department of Corrections and any hospital which meets the
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1 definition of rural hospital pursuant to s. 395.602 are exempt
2 from the assessment required in this subsection.

3 (c)1. The agency shall, by rule, establish fees for
4 hospitals and nursing homes based on an assessment of \$2 per
5 bed. However, no such facility shall be assessed more than a
6 total of \$500 under this subsection.

7 2. The agency shall, by rule, establish fees for
8 assisted living facilities based on an assessment of \$1 per
9 bed. However, no such facility shall be assessed more than a
10 total of \$150 under this subsection.

11 3. The agency shall, by rule, establish an annual fee
12 of \$150 for all other facilities and organizations listed in
13 paragraph (a).

14 (d) The agency shall, by rule, establish a facility
15 billing and collection process for the billing and collection
16 of the health facility fees authorized by this subsection.

17 (e) A health facility which is assessed a fee under
18 this subsection is subject to a fine of \$100 per day for each
19 day in which the facility is late in submitting its annual fee
20 up to maximum of the annual fee owed by the facility. A
21 facility which refuses to pay the fee or fine is subject to
22 the forfeiture of its license.

23 (f) The agency shall deposit in the Health Care Trust
24 Fund all health care facility assessments that are assessed
25 under this subsection and ~~proceeds from the~~
26 ~~certificate-of-need application fees.~~ The agency shall
27 transfer such funds to the Department of Health for an amount
28 ~~sufficient to maintain the aggregate funding of level for the~~
29 ~~local health councils as specified in the General~~
30 ~~Appropriations Act.~~ The remaining certificate-of-need
31 application fees shall be used only for the purpose of

1 administering the certificate-of-need program ~~Health Facility~~
2 ~~and Services Development Act.~~

3 (3) DUTIES AND RESPONSIBILITIES OF THE AGENCY.--

4 (a) The agency, ~~in conjunction with the local health~~
5 ~~councils,~~ is responsible for the coordinated planning of
6 health care services in the state.

7 (b) The agency shall develop and maintain a
8 comprehensive health care database for the purpose of health
9 planning and for certificate-of-need determinations. The
10 agency or its contractor is authorized to require the
11 submission of information from health facilities, health
12 service providers, and licensed health professionals which is
13 determined by the agency, through rule, to be necessary for
14 meeting the agency's responsibilities as established in this
15 section.

16 ~~(c) The agency shall assist personnel of the local~~
17 ~~health councils in providing an annual orientation to council~~
18 ~~members about council member responsibilities.~~

19 (c)(d) The Department of Health agency shall contract
20 with the local health councils for the services specified in
21 subsection (1). All contract funds shall be distributed
22 according to an allocation plan developed by the department
23 ~~agency that provides for a minimum and equal funding base for~~
24 ~~each local health council. Any remaining funds shall be~~
25 ~~distributed based on adjustments for workload. The agency may~~
26 ~~also make grants to or reimburse local health councils from~~
27 ~~federal funds provided to the state for activities related to~~
28 ~~those functions set forth in this section.~~The department
29 agency may withhold funds from a local health council or
30 cancel its contract with a local health council which does not
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1 meet performance standards agreed upon by the department
2 ~~agency~~ and local health councils.

3 Section 4. Subsections (1), (2), and (5) of section
4 408.034, Florida Statutes, are amended to read:

5 408.034 Duties and responsibilities of agency;
6 rules.--

7 (1) The agency is designated as the single state
8 agency to issue, revoke, or deny certificates of need and to
9 issue, revoke, or deny exemptions from certificate-of-need
10 review in accordance with ~~the district plans and~~ present and
11 future federal and state statutes. The agency is designated
12 as the state health planning agency for purposes of federal
13 law.

14 (2) In the exercise of its authority to issue licenses
15 to health care facilities and health service providers, as
16 provided under chapters 393, 395, and parts II and VI of
17 chapter 400, the agency may not issue a license to any health
18 care facility or health service provider that, ~~hospice, or~~
19 ~~part of a health care facility which~~ fails to receive a
20 certificate of need or an exemption for the licensed facility
21 or service.

22 (5) The agency shall establish by rule a
23 nursing-home-bed-need methodology that has a goal of
24 maintaining a subdistrict average occupancy rate of 94 percent
25 and that reduces the community nursing home bed need for the
26 areas of the state where the agency establishes pilot
27 community diversion programs through the Title XIX aging
28 waiver program.

29 Section 5. Section 408.035, Florida Statutes, is
30 amended to read:

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1 408.035 Review criteria.--The agency shall determine
2 the reviewability of applications and shall review
3 applications for certificate-of-need determinations for health
4 care facilities and health services in context with the
5 following criteria:

6 (1) The need for the health care facilities and health
7 services being proposed ~~in relation to the applicable district~~
8 ~~health plan.~~

9 (2) The availability, quality of care, accessibility,
10 and extent of utilization of existing health care facilities
11 and health services in the service district of the applicant.

12 (3) The ability of the applicant to provide quality of
13 care and the applicant's record of providing quality of care.

14 ~~(4) The need in the service district of the applicant~~
15 ~~for special health care services that are not reasonably and~~
16 ~~economically accessible in adjoining areas.~~

17 ~~(5) The needs of research and educational facilities,~~
18 ~~including, but not limited to, facilities with institutional~~
19 ~~training programs and community training programs for health~~
20 ~~care practitioners and for doctors of osteopathic medicine and~~
21 ~~medicine at the student, internship, and residency training~~
22 ~~levels.~~

23 (4)~~(6)~~ The availability of resources, including health
24 personnel, management personnel, and funds for capital and
25 operating expenditures, for project accomplishment and
26 operation.

27 (5)~~(7)~~ The extent to which the proposed services will
28 enhance access to health care for residents of the service
29 district.

30 (6)~~(8)~~ The immediate and long-term financial
31 feasibility of the proposal.

1 ~~(7)(9)~~ The extent to which the proposal will foster
2 competition that promotes quality and cost-effectiveness.

3 ~~(8)(10)~~ The costs and methods of the proposed
4 construction, including the costs and methods of energy
5 provision and the availability of alternative, less costly, or
6 more effective methods of construction.

7 ~~(9)(11)~~ The applicant's past and proposed provision of
8 health care services to Medicaid patients and the medically
9 indigent.

10 ~~(10)(12)~~ The applicant's designation as a Gold Seal
11 Program nursing facility pursuant to s. 400.235, when the
12 applicant is requesting additional nursing home beds at that
13 facility.

14 Section 6. Section 408.036, Florida Statutes, is
15 amended to read:

16 408.036 Projects subject to review; exemptions.--

17 (1) APPLICABILITY.--Unless exempt under subsection
18 (3), all health-care-related projects, as described in
19 paragraphs~~(a)-(e)(a)-(h)~~, are subject to review and must
20 file an application for a certificate of need with the agency.
21 The agency is exclusively responsible for determining whether
22 a health-care-related project is subject to review under ss.
23 408.031-408.045.

24 (a) The addition of beds in community nursing homes or
25 intermediate care facilities for the developmentally disabled
26 by new construction or alteration.

27 (b) The new construction or establishment of
28 additional health care facilities, including a replacement
29 health care facility when the proposed project site is not
30 located on the same site as or within 1 mile of the existing
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1 health care facility, if the number of beds in each licensed
2 bed category will not increase.

3 (c) The conversion from one type of health care
4 facility to another, including the conversion from a general
5 hospital, a specialty hospital, or a long-term care hospital.

6 ~~(d) An increase in the total licensed bed capacity of~~
7 ~~a health care facility.~~

8 ~~(d)(e)~~ The establishment of a hospice or hospice
9 inpatient facility, except as provided in s. 408.043.

10 ~~(f) The establishment of inpatient health services by~~
11 ~~a health care facility, or a substantial change in such~~
12 ~~services.~~

13 ~~(e)(g)~~ An increase in the number of beds for acute
14 care, ~~nursing home care beds, specialty burn units, neonatal~~
15 ~~intensive care units, comprehensive rehabilitation, mental~~
16 ~~health services, or hospital-based distinct part skilled~~
17 ~~nursing units, or at a long-term care hospital.~~

18 ~~(f)(h)~~ The establishment of tertiary health services,
19 including inpatient comprehensive rehabilitation services.

20 (g) An increase in the number of beds for acute care
21 in a hospital that is located in a low-growth county. A
22 low-growth county is defined as a county that has:

23 1. A hospital with an occupancy rate for licensed
24 acute care which has been below 60 percent for the previous 5
25 years;

26 2. Experienced a growth rate of 4 percent or less for
27 the most recent 3-year period for which data are available, as
28 determined using the population statistics published in the
29 most recent edition of the Florida Statistical Abstract; and
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1 3. A hospital that has combined gross revenues from
2 Medicaid and charity patients which exceed \$60 million per
3 year for the previous 2 years.

4
5 A hospital in a county that does not meet this definition is
6 subject to the exemption in subsection (3).

7 (2) PROJECTS SUBJECT TO EXPEDITED REVIEW.--Unless
8 exempt pursuant to subsection (3), projects subject to an
9 expedited review shall include, but not be limited to:

10 ~~(a) Research, education, and training programs.~~

11 ~~(b) Shared services contracts or projects.~~

12 (a)(c) A transfer of a certificate of need, except
13 that when an existing hospital is acquired by a purchaser, all
14 certificates of need issued to the hospital which are not yet
15 operational shall be acquired by the purchaser, without need
16 for a transfer.

17 (b) Replacement of a nursing home within the same
18 district, if the proposed project site is located within a
19 geographic area that contains at least 65 percent of the
20 facility's current residents and is within a 30-mile radius of
21 the replaced nursing home.

22 (c) Relocation of a portion of a nursing home's
23 licensed beds to a facility within the same district, if the
24 relocation is within a 30-mile radius of the existing facility
25 and the total number of nursing home beds in the district does
26 not increase.

27 ~~(d) A 50-percent increase in nursing home beds for a~~
28 ~~facility incorporated and operating in this state for at least~~
29 ~~60 years on or before July 1, 1988, which has a licensed~~
30 ~~nursing home facility located on a campus providing a variety~~
31 ~~of residential settings and supportive services. The~~

1 ~~increased nursing home beds shall be for the exclusive use of~~
2 ~~the campus residents. Any application on behalf of an~~
3 ~~applicant meeting this requirement shall be subject to the~~
4 ~~base fee of \$5,000 provided in s. 408.038.~~

5 ~~(e) Replacement of a health care facility when the~~
6 ~~proposed project site is located in the same district and~~
7 ~~within a 1-mile radius of the replaced health care facility.~~

8 ~~(f) The conversion of mental health services beds~~
9 ~~licensed under chapter 395 or hospital-based distinct part~~
10 ~~skilled nursing unit beds to general acute care beds; the~~
11 ~~conversion of mental health services beds between or among the~~
12 ~~licensed bed categories defined as beds for mental health~~
13 ~~services; or the conversion of general acute care beds to beds~~
14 ~~for mental health services.~~

15 ~~1. Conversion under this paragraph shall not establish~~
16 ~~a new licensed bed category at the hospital but shall apply~~
17 ~~only to categories of beds licensed at that hospital.~~

18 ~~2. Beds converted under this paragraph must be~~
19 ~~licensed and operational for at least 12 months before the~~
20 ~~hospital may apply for additional conversion affecting beds of~~
21 ~~the same type.~~

22
23 The agency shall develop rules to implement the provisions for
24 expedited review, including time schedule, application content
25 which may be reduced from the full requirements of s.
26 408.037(1), and application processing.

27 (3) EXEMPTIONS.--Upon request, the following projects
28 are subject to exemption from the provisions of subsection

29 (1):
30
31

1 ~~(a) For replacement of a licensed health care facility~~
2 ~~on the same site, provided that the number of beds in each~~
3 ~~licensed bed category will not increase.~~

4 (a)~~(b)~~ For hospice services or for swing beds in a
5 rural hospital, as defined in s. 395.602, in a number that
6 does not exceed one-half of its licensed beds.

7 (b)~~(c)~~ For the conversion of licensed acute care
8 hospital beds to Medicare and Medicaid certified skilled
9 nursing beds in a rural hospital, as defined in s. 395.602, so
10 long as the conversion of the beds does not involve the
11 construction of new facilities. The total number of skilled
12 nursing beds, including swing beds, may not exceed one-half of
13 the total number of licensed beds in the rural hospital as of
14 July 1, 1993. Certified skilled nursing beds designated under
15 this paragraph, excluding swing beds, shall be included in the
16 community nursing home bed inventory. A rural hospital that
17 ~~which~~ subsequently decertifies any acute care beds exempted
18 under this paragraph shall notify the agency of the
19 decertification, and the agency shall adjust the community
20 nursing home bed inventory accordingly.

21 (c)~~(d)~~ For the addition of nursing home beds at a
22 skilled nursing facility that is part of a retirement
23 community that provides a variety of residential settings and
24 supportive services and that has been incorporated and
25 operated in this state for at least 65 years on or before July
26 1, 1994. All nursing home beds must not be available to the
27 public but must be for the exclusive use of the community
28 residents.

29 ~~(e) For an increase in the bed capacity of a nursing~~
30 ~~facility licensed for at least 50 beds as of January 1, 1994,~~
31 ~~under part II of chapter 400 which is not part of a continuing~~

1 ~~care facility if, after the increase, the total licensed bed~~
2 ~~capacity of that facility is not more than 60 beds and if the~~
3 ~~facility has been continuously licensed since 1950 and has~~
4 ~~received a superior rating on each of its two most recent~~
5 ~~licensure surveys.~~

6 (d)~~(f)~~ For an inmate health care facility built by or
7 for the exclusive use of the Department of Corrections as
8 provided in chapter 945. This exemption expires when such
9 facility is converted to other uses.

10 ~~(g) For the termination of an inpatient health care~~
11 ~~service, upon 30 days' written notice to the agency.~~

12 ~~(h) For the delicensure of beds, upon 30 days' written~~
13 ~~notice to the agency. A request for exemption submitted under~~
14 ~~this paragraph must identify the number, the category of beds,~~
15 ~~and the name of the facility in which the beds to be~~
16 ~~delicensed are located.~~

17 ~~(i) For the provision of adult inpatient diagnostic~~
18 ~~cardiac catheterization services in a hospital.~~

19 ~~1. In addition to any other documentation otherwise~~
20 ~~required by the agency, a request for an exemption submitted~~
21 ~~under this paragraph must comply with the following criteria:~~

22 ~~a. The applicant must certify it will not provide~~
23 ~~therapeutic cardiac catheterization pursuant to the grant of~~
24 ~~the exemption.~~

25 ~~b. The applicant must certify it will meet and~~
26 ~~continuously maintain the minimum licensure requirements~~
27 ~~adopted by the agency governing such programs pursuant to~~
28 ~~subparagraph 2.~~

29 ~~c. The applicant must certify it will provide a~~
30 ~~minimum of 2 percent of its services to charity and Medicaid~~
31 ~~patients.~~

1 ~~2. The agency shall adopt licensure requirements by~~
2 ~~rule which govern the operation of adult inpatient diagnostic~~
3 ~~cardiac catheterization programs established pursuant to the~~
4 ~~exemption provided in this paragraph. The rules shall ensure~~
5 ~~that such programs:~~

6 ~~a. Perform only adult inpatient diagnostic cardiac~~
7 ~~catheterization services authorized by the exemption and will~~
8 ~~not provide therapeutic cardiac catheterization or any other~~
9 ~~services not authorized by the exemption.~~

10 ~~b. Maintain sufficient appropriate equipment and~~
11 ~~health personnel to ensure quality and safety.~~

12 ~~c. Maintain appropriate times of operation and~~
13 ~~protocols to ensure availability and appropriate referrals in~~
14 ~~the event of emergencies.~~

15 ~~d. Maintain appropriate program volumes to ensure~~
16 ~~quality and safety.~~

17 ~~e. Provide a minimum of 2 percent of its services to~~
18 ~~charity and Medicaid patients each year.~~

19 ~~3.a. The exemption provided by this paragraph shall~~
20 ~~not apply unless the agency determines that the program is in~~
21 ~~compliance with the requirements of subparagraph 1. and that~~
22 ~~the program will, after beginning operation, continuously~~
23 ~~comply with the rules adopted pursuant to subparagraph 2. The~~
24 ~~agency shall monitor such programs to ensure compliance with~~
25 ~~the requirements of subparagraph 2.~~

26 ~~b.(I) The exemption for a program shall expire~~
27 ~~immediately when the program fails to comply with the rules~~
28 ~~adopted pursuant to sub-subparagraphs 2.a., b., and c.~~

29 ~~(II) Beginning 18 months after a program first begins~~
30 ~~treating patients, the exemption for a program shall expire~~
31

1 ~~when the program fails to comply with the rules adopted~~
2 ~~pursuant to sub-subparagraphs 2.d. and e.~~

3 ~~(III) If the exemption for a program expires pursuant~~
4 ~~to sub-sub-subparagraph (I) or sub-sub-subparagraph (II), the~~
5 ~~agency shall not grant an exemption pursuant to this paragraph~~
6 ~~for an adult inpatient diagnostic cardiac catheterization~~
7 ~~program located at the same hospital until 2 years following~~
8 ~~the date of the determination by the agency that the program~~
9 ~~failed to comply with the rules adopted pursuant to~~
10 ~~subparagraph 2.~~

11 (e)~~(j)~~ For mobile surgical facilities and related
12 health care services provided under contract with the
13 Department of Corrections or a private correctional facility
14 operating pursuant to chapter 957.

15 (f)~~(k)~~ For state veterans' nursing homes operated by
16 or on behalf of the Florida Department of Veterans' Affairs in
17 accordance with part II of chapter 296 for which at least 50
18 percent of the construction cost is federally funded and for
19 which the Federal Government pays a per diem rate not to
20 exceed one-half of the cost of the veterans' care in such
21 state nursing homes. These beds shall not be included in the
22 nursing home bed inventory.

23 (g)~~(l)~~ For combination within one nursing home
24 facility of the beds or services authorized by two or more
25 certificates of need issued in the same planning subdistrict.
26 An exemption granted under this paragraph shall extend the
27 validity period of the certificates of need to be consolidated
28 by the length of the period beginning upon submission of the
29 exemption request and ending with issuance of the exemption.
30 The longest validity period among the certificates shall be
31 applicable to each of the combined certificates.

1 (h)~~(m)~~ For division into two or more nursing home
2 facilities of beds or services authorized by one certificate
3 of need issued in the same planning subdistrict. An exemption
4 granted under this paragraph shall extend the validity period
5 of the certificate of need to be divided by the length of the
6 period beginning upon submission of the exemption request and
7 ending with issuance of the exemption.

8 (i)~~(n)~~ For the addition of hospital beds licensed
9 under chapter 395 for comprehensive rehabilitation acute care,
10 ~~mental health services, or a hospital-based distinct part~~
11 ~~skilled nursing unit~~ in a number that may not exceed 10 total
12 beds or 10 percent of the licensed capacity ~~of the bed~~
13 ~~category being expanded~~, whichever is greater. ~~Beds for~~
14 ~~specialty burn units, neonatal intensive care units, or~~
15 ~~comprehensive rehabilitation, or at a long-term care hospital,~~
16 ~~may not be increased under this paragraph.~~

17 1. In addition to any other documentation otherwise
18 required by the agency, a request for exemption submitted
19 under this paragraph must:

20 a. Certify that the prior 12-month average occupancy
21 rate for the ~~category of~~ licensed beds being expanded ~~at the~~
22 ~~facility~~ meets or exceeds 80 percent ~~or, for a hospital-based~~
23 ~~distinct part skilled nursing unit, the prior 12-month average~~
24 ~~occupancy rate meets or exceeds 96 percent.~~

25 b. Certify that the ~~any~~ beds ~~of the same type~~
26 ~~authorized for the facility under this paragraph before the~~
27 ~~date of the current request for an exemption~~ have been
28 licensed and operational for at least 12 months.

29 2. The timeframes and monitoring process specified in
30 s. 408.040(2)(a)-(c) apply to any exemption issued under this
31 paragraph.

1 3. The agency shall count beds authorized under this
2 paragraph as approved beds in the published inventory of
3 hospital beds until the beds are licensed.

4 ~~(o) For the addition of acute care beds, as authorized~~
5 ~~by rule consistent with s. 395.003(4), in a number that may~~
6 ~~not exceed 10 total beds or 10 percent of licensed bed~~
7 ~~capacity, whichever is greater, for temporary beds in a~~
8 ~~hospital that has experienced high seasonal occupancy within~~
9 ~~the prior 12-month period or in a hospital that must respond~~
10 ~~to emergency circumstances.~~

11 (j)(p) For the addition of nursing home beds licensed
12 under chapter 400 in a number not exceeding 10 total beds or
13 10 percent of the number of beds licensed in the facility
14 being expanded, whichever is greater; or, for the addition of
15 nursing home beds licensed under chapter 400 at a facility
16 that has been designated as a Gold Seal nursing home under s.
17 400.235 in a number not exceeding 20 total beds or 10 percent
18 of the number of licensed beds in the facility being expanded,
19 whichever is greater.

20 1. In addition to any other documentation required by
21 the agency, a request for exemption submitted under this
22 paragraph must:

23 a. ~~Effective until June 30, 2001,~~Certify that the
24 facility has not had any class I or class II deficiencies
25 within the 30 months preceding the request for addition.

26 b. ~~Effective on July 1, 2001, certify that the~~
27 ~~facility has been designated as a Gold Seal nursing home under~~
28 ~~s. 400.235.~~

29 b.c. Certify that the prior 12-month average occupancy
30 rate for the nursing home beds at the facility meets or
31 exceeds 96 percent.

1 ~~c.d.~~ Certify that any beds authorized for the facility
2 under this paragraph before the date of the current request
3 for an exemption have been licensed and operational for at
4 least 12 months.

5 2. The timeframes and monitoring process specified in
6 s. 408.040(2)(a)-(c) apply to any exemption issued under this
7 paragraph.

8 3. The agency shall count beds authorized under this
9 paragraph as approved beds in the published inventory of
10 nursing home beds until the beds are licensed.

11 (k) For the establishment of:

12 1. A Level II neonatal intensive care unit with at
13 least 10 beds, upon documentation to the agency that the
14 applicant hospital had a minimum of 1,500 births during the
15 previous 12 months; or

16 2. A Level III neonatal intensive care unit with at
17 least 15 beds, upon documentation to the agency that the
18 applicant hospital has a Level II neonatal intensive care unit
19 of at least 10 beds and had a minimum of 3,500 births during
20 the previous 12 months,

21
22 if the applicant demonstrates that it meets the requirements
23 for quality of care, nurse staffing, physician staffing,
24 physical plant, equipment, emergency transportation, and data
25 reporting found in agency certificate-of-need rules for Level
26 II and Level III neonatal intensive care units and if the
27 applicant commits to the provision of services to Medicaid and
28 charity patients at a level equal to or greater than the
29 district average. Such a commitment is subject to s. 408.040.

30 ~~(q) For establishment of a specialty hospital offering~~
31 ~~a range of medical service restricted to a defined age or~~

1 ~~gender group of the population or a restricted range of~~
2 ~~services appropriate to the diagnosis, care, and treatment of~~
3 ~~patients with specific categories of medical illnesses or~~
4 ~~disorders, through the transfer of beds and services from an~~
5 ~~existing hospital in the same county.~~

6 ~~(r) For the conversion of hospital-based Medicare and~~
7 ~~Medicaid certified skilled nursing beds to acute care beds, if~~
8 ~~the conversion does not involve the construction of new~~
9 ~~facilities.~~

10 ~~(s)1. For an adult open-heart surgery program to be~~
11 ~~located in a new hospital provided the new hospital is being~~
12 ~~established in the location of an existing hospital with an~~
13 ~~adult open-heart surgery program, the existing hospital and~~
14 ~~the existing adult open-heart surgery program are being~~
15 ~~relocated to a replacement hospital, and the replacement~~
16 ~~hospital will utilize a closed-staff model. A hospital is~~
17 ~~exempt from the certificate-of-need review for the~~
18 ~~establishment of an open-heart surgery program if the~~
19 ~~application for exemption submitted under this paragraph~~
20 ~~complies with the following criteria:~~

21 ~~a. The applicant must certify that it will meet and~~
22 ~~continuously maintain the minimum Florida Administrative Code~~
23 ~~and any future licensure requirements governing adult~~
24 ~~open-heart programs adopted by the agency, including the most~~
25 ~~current guidelines of the American College of Cardiology and~~
26 ~~American Heart Association Guidelines for Adult Open Heart~~
27 ~~Programs.~~

28 ~~b. The applicant must certify that it will maintain~~
29 ~~sufficient appropriate equipment and health personnel to~~
30 ~~ensure quality and safety.~~

31

1 ~~c. The applicant must certify that it will maintain~~
2 ~~appropriate times of operation and protocols to ensure~~
3 ~~availability and appropriate referrals in the event of~~
4 ~~emergencies.~~

5 ~~d. The applicant is a newly licensed hospital in a~~
6 ~~physical location previously owned and licensed to a hospital~~
7 ~~performing more than 300 open-heart procedures each year,~~
8 ~~including heart transplants.~~

9 ~~e. The applicant must certify that it can perform more~~
10 ~~than 300 diagnostic cardiac catheterization procedures per~~
11 ~~year, combined inpatient and outpatient, by the end of the~~
12 ~~third year of its operation.~~

13 ~~f. The applicant's payor mix at a minimum reflects the~~
14 ~~community average for Medicaid, charity care, and self-pay~~
15 ~~patients or the applicant must certify that it will provide a~~
16 ~~minimum of 5 percent of Medicaid, charity care, and self-pay~~
17 ~~to open-heart-surgery patients.~~

18 ~~g. If the applicant fails to meet the established~~
19 ~~criteria for open-heart programs or fails to reach 300~~
20 ~~surgeries per year by the end of its third year of operation,~~
21 ~~it must show cause why its exemption should not be revoked.~~

22 ~~h. In order to ensure continuity of available~~
23 ~~services, the applicant of the newly licensed hospital may~~
24 ~~apply for this certificate of need before taking possession of~~
25 ~~the physical facilities. The effective date of the~~
26 ~~certificate of need will be concurrent with the effective date~~
27 ~~of the newly issued hospital license.~~

28 ~~2. By December 31, 2004, and annually thereafter, the~~
29 ~~agency shall submit a report to the Legislature providing~~
30 ~~information concerning the number of requests for exemption~~
31

1 ~~received under this paragraph and the number of exemptions~~
2 ~~granted or denied.~~

3 ~~3. This paragraph is repealed effective January 1,~~
4 ~~2008.~~

5 (1)(t)1. For the provision of adult open-heart
6 services in a hospital located within the boundaries of a
7 health service planning district, as defined in s. 408.032(5),
8 which has experienced an annual net out-migration of at least
9 600 open-heart-surgery cases for 3 consecutive years according
10 to the most recent data reported to the agency, and the
11 district's population per licensed and operational open-heart
12 programs exceeds the state average of population per licensed
13 and operational open-heart programs by at least 25 percent
14 ~~Palm Beach, Polk, Martin, St. Lucie, and Indian River Counties~~
15 ~~if the following conditions are met: The exemption must be~~
16 ~~based upon objective criteria and address and solve the twin~~
17 ~~problems of geographic and temporal access. All hospitals~~
18 within a health service planning district which meet the
19 criteria reference in sub-subparagraphs 2.a.-h. shall be
20 eligible for this exemption on July 1, 2004, and shall receive
21 the exemption upon filing for it and subject to the following:

22 a. A hospital that has received a notice of intent to
23 grant a certificate of need or a final order of the agency
24 granting a certificate of need for the establishment of an
25 open-heart-surgery program is entitled to receive a letter of
26 exemption for the establishment of an adult open-heart-surgery
27 program upon filing a request for exemption and complying with
28 the criteria enumerated in sub-subparagraphs 2.a.-h., and is
29 entitled to immediately commence operation of the program.

30 b. An otherwise eligible hospital that has not
31 received a notice of intent to grant a certificate of need or

1 a final order of the agency granting a certificate of need for
2 the establishment of an open-heart-surgery program is entitled
3 to immediately receive a letter of exemption for the
4 establishment of an adult open-heart-surgery program upon
5 filing a request for exemption and complying with the criteria
6 enumerated in sub-subparagraphs 2.a.-h., but is not entitled
7 to commence operation of its program until December 31, 2006.

8 2. A hospital shall be exempt from the
9 certificate-of-need review for the establishment of an
10 open-heart-surgery program when the application for exemption
11 submitted under this paragraph complies with the following
12 criteria:

13 a. The applicant must certify that it will meet and
14 continuously maintain the minimum licensure requirements
15 adopted by the agency governing adult open-heart programs,
16 including the most current guidelines of the American College
17 of Cardiology and American Heart Association Guidelines for
18 Adult Open Heart Programs.

19 b. The applicant must certify that it will maintain
20 sufficient appropriate equipment and health personnel to
21 ensure quality and safety.

22 c. The applicant must certify that it will maintain
23 appropriate times of operation and protocols to ensure
24 availability and appropriate referrals in the event of
25 emergencies.

26 d. The applicant can demonstrate that it has
27 discharged at least 300 inpatients with a principal diagnosis
28 of ischemic heart disease for the most recent 12-month period
29 as reported to the agency ~~is referring 300 or more patients~~
30 ~~per year from the hospital, including the emergency room, for~~
31 ~~cardiac services at a hospital with cardiac services, or that~~

1 ~~the average wait for transfer for 50 percent or more of the~~
2 ~~cardiac patients exceeds 4 hours.~~

3 e. The applicant is a general acute care hospital that
4 is in operation for 3 years or more.

5 f. The applicant is performing more than 300
6 diagnostic cardiac catheterization procedures per year,
7 combined inpatient and outpatient.

8 g. The applicant's payor mix at a minimum reflects the
9 community average for Medicaid, charity care, and self-pay
10 patients or the applicant must certify that it will provide a
11 minimum of 5 percent of Medicaid, charity care, and self-pay
12 to open-heart-surgery patients.

13 h. If the applicant fails to meet the established
14 criteria for open-heart programs or fails to reach 300
15 surgeries per year by the end of its third year of operation,
16 it must show cause why its exemption should not be revoked.

17 ~~3.2.~~ By December 31, 2004, and annually thereafter,
18 the agency ~~for Health Care Administration~~ shall submit a
19 report to the Legislature providing information concerning the
20 number of requests for exemption it has received under this
21 paragraph during the calendar year and the number of
22 exemptions it has granted or denied during the calendar year.

23 (m) For the provision of percutaneous coronary
24 intervention for patients presenting with emergency myocardial
25 infarctions in a hospital without an approved adult
26 open-heart-surgery program. In addition to any other
27 documentation required by the agency, a request for an
28 exemption submitted under this paragraph must comply with the
29 following:

30 1. The applicant must certify that it will meet and
31 continuously maintain the requirements adopted by the agency

1 for the provisions of these services. These licensure
2 requirements must be adopted by rule pursuant to ss.
3 120.536(1) and 120.54 and must be consistent with the
4 guidelines published by the American College of Cardiology and
5 the American Heart Association for the provision of
6 percutaneous coronary interventions in hospitals without adult
7 open-heart services. At a minimum, the rules shall require
8 that:

9 a. Cardiologists be experienced interventionalists who
10 have performed a minimum of 75 interventions within the
11 previous 12 months.

12 b. The hospital provide a minimum of 36 emergency
13 interventions annually in order to continue to provide the
14 service.

15 c. The hospital offer sufficient physician, nursing,
16 and laboratory staff to provide the services 24 hours a day, 7
17 days a week.

18 d. Nursing and technical staff have demonstrated
19 experience in handling acutely ill patients requiring
20 intervention based on previous experience in dedicated
21 interventional laboratories or surgical centers.

22 e. Cardiac care nursing staff be adept in hemodynamic
23 monitoring and Intra-aortic Balloon Pump management.

24 f. Formalized written transfer agreements be developed
25 with a hospital with an adult open-heart-surgery program and
26 written transport protocols be in place to ensure safe and
27 efficient transfer of a patient within 60 minutes. Transfer
28 and transport agreements must be received and tested, with
29 appropriate documentation maintained at least every 3 months.

30 g. Hospitals implementing the service first undertake
31 a training program of 3 to 6 months' duration, which includes

1 establishing standard and testing logistics, creating quality
2 assessment and error management practices, and formalizing
3 patient-selection criteria.

4 2. The applicant must certify that it will at all
5 times use the patient-selection criteria for the performance
6 of primary angioplasty at hospitals without adult
7 open-heart-surgery programs issued by the American College of
8 Cardiology and the American Heart Association. At a minimum,
9 these criteria must provide for:

10 a. Avoidance of interventions in hemodynamically
11 stable patients who have identified symptoms or medical
12 histories.

13 b. Transfer of patients who have a history of coronary
14 disease and clinical presentation of hemodynamic instability.

15 3. The applicant must agree to submit to the agency a
16 quarterly report detailing patient characteristics, treatment,
17 and outcomes for all patients receiving emergency percutaneous
18 coronary interventions pursuant to this paragraph. This report
19 must be submitted within 15 days after the close of each
20 calendar quarter.

21 4. The exemption provided by this paragraph does not
22 apply unless the agency determines that the hospital has taken
23 all necessary steps to be in compliance with all requirements
24 of this paragraph, including the training program required
25 under sub-subparagraph 1.g.

26 5. If the hospital fails to continuously comply with
27 the requirements of sub-subparagraphs 1.c.-f. and
28 subparagraphs 2. and 3., this exemption immediately expires.

29 6. If the hospital fails to meet the volume
30 requirements of sub-subparagraphs 1.a. and b. within 18 months
31

1 after the program begins offering the service, this exemption
2 immediately expires.

3
4 If the exemption for this service expires under subparagraph
5 5. or subparagraph 6., the agency may not grant another
6 exemption for this service to the same hospital for 2 years
7 and then only upon a showing that the hospital will remain in
8 compliance with the requirements of this paragraph through a
9 demonstration of corrections to the deficiencies that caused
10 the exemption to expire. Compliance with this paragraph
11 includes compliance with the rules adopted pursuant to this
12 paragraph.

13 (n) For the addition of mental health services or beds
14 if the applicant commits to providing services to Medicaid or
15 charity care patients at a level equal to or greater than the
16 district average. Such a commitment is subject to s. 408.040.

17 (o) For replacement of a licensed nursing home on the
18 same site, or within 3 miles of the same site, if the number
19 of licensed beds does not increase.

20 (p) For consolidation or combination of licensed
21 nursing homes or transfer of beds between licensed nursing
22 homes within the same planning subdistrict, by providers that
23 operate multiple nursing homes within that planning
24 subdistrict, if there is no increase in the planning
25 subdistrict total number of nursing home beds and the site of
26 the relocation is not more than 30 miles from the original
27 location.

28 (q) For beds in state mental health treatment
29 facilities operated under s. 394.455(30) and state mental
30 health forensic facilities operated under s. 916.106(8).

31

1 (r) For beds in state developmental services
2 institutions as defined in s. 393.063.

3 (4) REQUESTS FOR EXEMPTION.--A request for exemption
4 under subsection (3) may be made at any time and is not
5 subject to the batching requirements of this section. The
6 request shall be supported by such documentation as the agency
7 requires by rule. The agency shall assess a fee of \$250 for
8 each request for exemption submitted under subsection (3).

9 (5) NOTIFICATION.--Health care facilities and
10 providers must provide to the agency notification of:

11 (a) Replacement of a health care facility when the
12 proposed project site is located in the same district and on
13 the existing site or within a 1-mile radius of the replaced
14 health care facility, if the number and type of beds do not
15 increase.

16 (b) The termination of a health care service, upon 30
17 days' written notice to the agency.

18 (c) The addition or delicensure of beds.

19
20 Notification under this subsection may be made by electronic,
21 facsimile, or written means at any time before the described
22 action has been taken.

23 Section 7. Section 408.0361, Florida Statutes, is
24 amended to read:

25 408.0361 Cardiology services and burn unit licensure
26 ~~Diagnostic cardiac catheterization services providers;~~
27 ~~compliance with guidelines and requirements.--~~

28 (1) Each provider of diagnostic cardiac
29 catheterization services shall comply with ~~the requirements of~~
30 ~~s. 408.036(3)(i)2.a.-d., and rules adopted by~~ of the agency
31 which establish licensure standards for Health Care

1 ~~Administration~~ governing the operation of adult inpatient
2 diagnostic cardiac catheterization programs. The rules must
3 ensure that the programs:

4 (a) Comply with,~~including~~ the most recent guidelines
5 of the American College of Cardiology and American Heart
6 Association Guidelines for Cardiac Catheterization and Cardiac
7 Catheterization Laboratories.

8 (b) Perform only adult inpatient diagnostic cardiac
9 catheterization services and do not provide therapeutic
10 cardiac catheterization or any other cardiology services.

11 (c) Maintain sufficient appropriate equipment and
12 health care personnel to ensure quality and safety.

13 (d) Maintain appropriate times of operation and
14 protocols to ensure availability and appropriate referrals in
15 the event of emergencies.

16 (e) Demonstrate a plan to provide services to Medicaid
17 and charity patients.

18 (2) Each provider of adult interventional cardiology
19 services or operator of a burn unit shall comply with rules
20 adopted by the agency which establish licensure standards that
21 govern the provision of adult interventional cardiology
22 services or the operation of a burn unit. Such rules must
23 consider, at a minimum, staffing, equipment, physical plant,
24 operating protocols, the provision of services to Medicaid and
25 charity patients, accreditation, licensure period and fees,
26 and enforcement of minimum standards. The certificate-of-need
27 rules for adult interventional cardiology services and burn
28 units in effect on June 30, 2004, are ratified pursuant to
29 this subsection and shall remain in effect and be enforceable
30 by the agency until the licensure rules are adopted. Existing
31 providers and any provider with a notice of intent to grant a

1 certificate of need or a final order of the agency granting a
2 a certificate of need for adult interventional cardiology
3 services or burn units shall be considered grandfathered-in
4 and shall receive a license for their programs effective on
5 July 1, 2004. That licensure shall remain valid for at least 3
6 years or a period specified in the rule, whichever is longer,
7 but such programs must meet licensure standards applicable to
8 existing programs for every subsequent licensure period.

9 (3) In establishing rules for adult interventional
10 cardiology services, the agency shall include provisions that
11 allow for:

12 (a) Establishment of two hospital program licensure
13 levels: a Level I program authorizing the performance of adult
14 primary percutaneous cardiac intervention for emergent
15 patients without onsite cardiac surgery and a Level II program
16 authorizing the performance of percutaneous cardiac
17 intervention with onsite cardiac surgery.

18 (b) For a hospital seeking a Level I program,
19 demonstration that, for the most recent 12-month period as
20 reported to the agency, it has provided a minimum of 300 adult
21 inpatient and outpatient diagnostic cardiac catheterizations
22 or has transferred at least 300 inpatients with the principal
23 diagnosis of ischemic heart disease and that it has a
24 formalized, written transfer agreement with a hospital that
25 has a Level II program, including written transport protocols
26 to ensure safe and efficient transfer of a patient within 60
27 minutes.

28 (c) For a hospital seeking a Level II program,
29 demonstration that it has discharged at least 800 patients
30 with the principal diagnosis of ischemic heart disease.

31

1 (d) Compliance with the most recent guidelines of the
2 American College of Cardiology and American Heart Association
3 guidelines for staffing, physician training and experience,
4 operating procedures, equipment, physical plant, and
5 patient-selection criteria to ensure patient quality and
6 safety.

7 (e) Establishment of appropriate hours of operation
8 and protocols to ensure availability and timely referral in
9 the event of emergencies.

10 (f) Demonstration of a plan to provide services to
11 Medicaid and charity patients.

12 (4) The agency shall establish a technical advisory
13 panel to develop procedures and standards for measuring
14 outcomes of interventional cardiac programs. Members of the
15 panel shall include representatives of the Florida Hospital
16 Association, the Florida Society of Thoracic and
17 Cardiovascular Surgeons, the Florida Chapter of the American
18 College of Cardiology, and the Florida Chapter of the American
19 Heart Association and others who have experience in statistics
20 and outcome measurement. Based upon recommendations from the
21 panel, the agency shall develop and adopt for the
22 interventional cardiac programs rules that include at least
23 the following:

24 (a) A standard data set consisting primarily of data
25 elements reported to the agency in accordance with s. 408.061.

26 (b) A risk-adjustment procedure that accounts for the
27 variations in severity and case mix found in hospitals in this
28 state.

29 (c) Outcome standards specifying expected levels of
30 performance in Level I and Level II adult interventional
31 cardiology services. Such standards may include, but are not

1 limited to, inhospital mortality, infection rates, nonfatal
2 myocardial infarctions, length of stay, postoperative bleeds,
3 and returns to surgery.

4 (d) Specific steps to be taken by the agency and
5 licensing hospitals that do not meet the outcome standards
6 within specified time periods, including time periods for
7 detailed case reviews and development and implementation of
8 corrective action plans.

9 (9) The Secretary of Health Care Administration shall
10 appoint an advisory group to study the issue of replacing
11 certificate-of-need review of organ transplant programs under
12 this chapter with licensure regulation of organ transplant
13 programs under chapter 395. The advisory group shall include
14 three representatives of organ transplant providers, one
15 representative of an organ procurement organization, one
16 representative of the Division of Health Quality Assurance,
17 one representative of Medicaid, and one advocate for organ
18 transplant patients. The advisory group shall, at a minimum,
19 make recommendations regarding access to organs, delivery of
20 services to Medicaid and charity patients, staff training, and
21 resource requirements for organ transplant programs in a
22 report due to the secretary and the Legislature by July 1,
23 2005.

24 (10) The Secretary of Health Care Administration shall
25 appoint a work group to study certificate-of-need regulations
26 and changing market conditions related to the supply and
27 distribution of hospital beds. The assessment by the work
28 group shall include, but need not be limited to:

29 (a) The appropriateness of current certificate-of-need
30 methodologies and other criteria for evaluating proposals for
31 new hospitals and transfers of beds to new sites.

1 (b) Additional factors that should be considered,
2 including the viability of safety-net services, the extent of
3 market competition, and the accessibility of hospital
4 services.

5
6 The workgroup shall, by January 1, 2005, submit to the
7 secretary and the Legislature a report identifying specific
8 program areas and recommending needed changes in statutes and
9 rules.

10 Section 8. Section 408.038, Florida Statutes, is
11 amended to read:

12 408.038 Fees.--The agency shall assess fees on
13 certificate-of-need applications. Such fees shall be for the
14 purpose of funding the ~~functions of the local health councils~~
15 ~~and the~~ activities of the agency and shall be allocated as
16 provided in s. 408.033. The fee shall be determined as
17 follows:

18 (1) A minimum base fee of ~~\$10,000~~\$5,000.

19 (2) In addition to the base fee of ~~\$10,000~~\$5,000,
20 0.015 of each dollar of proposed expenditure, except that a
21 fee may not exceed ~~\$50,000~~\$22,000.

22 Section 9. Subsections (1), paragraph (a) of
23 subsection (3), and paragraph (a) and (b) of subsection (4) of
24 section 408.039, are amended to read:

25 408.039 Review process.--The review process for
26 certificates of need shall be as follows:

27 (1) REVIEW CYCLES.--The agency by rule shall provide
28 for applications to be submitted on a timetable or cycle
29 basis; provide for review on a timely basis; and provide for
30 all completed applications pertaining to similar types of
31 services or facilities affecting the same service district to

1 be considered in relation to each other no less often than
2 annually ~~two times a year~~.

3 (3) APPLICATION PROCESSING.--

4 (a) An applicant shall file an application with the
5 agency, and shall furnish a copy of the application to ~~the~~
6 ~~local health council and~~ the agency. Within 15 days after the
7 applicable application filing deadline established by agency
8 rule, the staff of the agency shall determine if the
9 application is complete. If the application is incomplete,
10 the staff shall request specific information from the
11 applicant necessary for the application to be complete;
12 however, the staff may make only one such request. If the
13 requested information is not filed with the agency within 21
14 days after ~~of~~ the receipt of the staff's request, the
15 application shall be deemed incomplete and deemed withdrawn
16 from consideration.

17 (4) STAFF RECOMMENDATIONS.--

18 (a) The agency's review of and final agency action on
19 applications shall be in accordance with ~~the district health~~
20 ~~plan, and~~ statutory criteria, and the implementing
21 administrative rules. In the application review process, the
22 agency shall give a preference, as defined by rule of the
23 agency, to an applicant which proposes to develop a nursing
24 home in a nursing home geographically underserved area.

25 (b) Within 60 days after all the applications in a
26 review cycle are determined to be complete, the agency shall
27 issue its State Agency Action Report and Notice of Intent to
28 grant a certificate of need for the project in its entirety,
29 to grant a certificate of need for identifiable portions of
30 the project, or to deny a certificate of need. The State
31 Agency Action Report shall set forth in writing its findings

1 of fact and determinations upon which its decision is based.
2 ~~If a finding of fact or determination by the agency is counter~~
3 ~~to the district health plan of the local health council, the~~
4 ~~agency shall provide in writing its reason for its findings,~~
5 ~~item by item, to the local health council.~~ If the agency
6 intends to grant a certificate of need, the State Agency
7 Action Report or the Notice of Intent shall also include any
8 conditions which the agency intends to attach to the
9 certificate of need. The agency shall designate by rule a
10 senior staff person, other than the person who issues the
11 final order, to issue State Agency Action Reports and Notices
12 of Intent.

13 Section 10. Section 408.040, Florida Statutes, is
14 amended to read:

15 408.040 Conditions and monitoring.--

16 (1)(a) The agency may issue a certificate of need, or
17 an exemption, predicated upon statements of intent expressed
18 by an applicant in the application for a certificate of need
19 or an exemption. Any conditions imposed on a certificate of
20 need or an exemption based on such statements of intent shall
21 be stated on the face of the certificate of need or in the
22 exemption approval.

23 (b) The agency may consider, in addition to the other
24 criteria specified in s. 408.035, a statement of intent by the
25 applicant that a specified percentage of the annual patient
26 days at the facility will be utilized by patients eligible for
27 care under Title XIX of the Social Security Act. Any
28 certificate of need issued to a nursing home in reliance upon
29 an applicant's statements that a specified percentage of
30 annual patient days will be utilized by residents eligible for
31 care under Title XIX of the Social Security Act must include a

1 statement that such certification is a condition of issuance
2 of the certificate of need. The certificate-of-need program
3 shall notify the Medicaid program office and the Department of
4 Elderly Affairs when it imposes conditions as authorized in
5 this paragraph in an area in which a community diversion pilot
6 project is implemented.

7 (c) A certificateholder or an exemption holder may
8 apply to the agency for a modification of conditions imposed
9 under paragraph (a) or paragraph (b). If the holder of a
10 certificate of need or an exemption demonstrates good cause
11 why the certificate or exemption should be modified, the
12 agency shall reissue the certificate of need or exemption with
13 such modifications as may be appropriate. The agency shall by
14 rule define the factors constituting good cause for
15 modification.

16 (d) If the holder of a certificate of need or an
17 exemption fails to comply with a condition upon which the
18 issuance of the certificate or exemption was predicated, the
19 agency may assess an administrative fine against the
20 certificateholder or exemption holder in an amount not to
21 exceed \$1,000 per failure per day. Failure to annually report
22 compliance with any condition upon which the issuance of the
23 certificate or exemption was predicated constitutes
24 noncompliance. In assessing the penalty, the agency shall take
25 into account as mitigation the degree of noncompliance
26 ~~relative lack of severity of a particular failure.~~ Proceeds
27 of such penalties shall be deposited in the Public Medical
28 Assistance Trust Fund.

29 (2)(a) Unless the applicant has commenced
30 construction, if the project provides for construction, unless
31 the applicant has incurred an enforceable capital expenditure

1 commitment for a project, if the project does not provide for
2 construction, or unless subject to paragraph (b), a
3 certificate of need shall terminate 18 months after the date
4 of issuance. The agency shall monitor the progress of the
5 holder of the certificate of need in meeting the timetable for
6 project development specified in the application ~~with the~~
7 ~~assistance of the local health council as specified in s.~~
8 ~~408.033(1)(b)5-~~, and may revoke the certificate of need, if
9 the holder of the certificate is not meeting such timetable
10 and is not making a good-faith effort, as defined by rule, to
11 meet it.

12 (b) A certificate of need issued to an applicant
13 holding a provisional certificate of authority under chapter
14 651 shall terminate 1 year after the applicant receives a
15 valid certificate of authority from the Office of Insurance
16 Regulation of the Financial Services Commission.

17 (c) The certificate-of-need validity period for a
18 project shall be extended by the agency, to the extent that
19 the applicant demonstrates to the satisfaction of the agency
20 that good-faith commencement of the project is being delayed
21 by litigation or by governmental action or inaction with
22 respect to regulations or permitting precluding commencement
23 of the project.

24 (3) The agency shall require the submission of an
25 executed architect's certification of final payment for each
26 certificate-of-need project approved by the agency. Each
27 project that involves construction shall submit such
28 certification to the agency within 30 days following
29 completion of construction.

30 Section 11. Subsection (5) of section 408.043, Florida
31 Statutes, is repealed.

1 Section 12. Section 408.0455, Florida Statutes, is
2 amended to read:

3 408.0455 Rules; pending proceedings.--The rules of the
4 agency in effect on June 30, 2004 ~~1997~~, shall remain in effect
5 and shall be enforceable by the agency with respect to ss.
6 408.031-408.045 until such rules are repealed or amended by
7 the agency, ~~and no judicial or administrative proceeding~~
8 ~~pending on July 1, 1997, shall be abated as a result of the~~
9 ~~provisions of ss. 408.031-408.043(1) and (2); s. 408.044; or~~
10 ~~s. 408.045.~~

11 Section 13. This act shall take effect July 1, 2004.

12
13 STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
14 COMMITTEE SUBSTITUTE FOR
15 CS/SB 2606

16 Adds an additional criterion that an increase in the number of
17 beds for acute care in a hospital located in a low-growth
18 county is subject to comparative review under certificate of
19 need provisions.

20 Changes the effective date from December 1, 2006 to December
21 31, 2006 to commence operation of an adult open-heart-surgery
22 program.